



## EC DECLARATION OF CONFORMITY

**According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III**

**Manufacturer:** ACRO BIOTECH LLC 9500 7th Street Unit M Rancho Cucamonga,  
CA 91730

**Product:** HBsAg/HCV/HIV 1.2 Combo Rapid Test Cassette WB/S/P

**Product code:** IBCH-435

**Classification:** Other device (all devices except Annex II and self-testing devices)

**European Representative:**

**Name:** MedNet EC-REP GmbH

**Address:** Borkstrasse 10, 48163 Muenster, Germany

**We herewith declare on our sole responsibility that all batches of the above mentioned product are conform with the Essential Requirements of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.**

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27  
October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012—2019, EN 13975:2003,  
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO  
17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Montclair on 24/05/2022

Dr. Mathias Volk  
Chemist, Safety officer

ACRO BIOTECH, INC

**ACRO BIOTECH, Inc.**

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